Johns Hopkins University

A GUIDE TO COMPLIANCE WITH THE SINGLE IRB MANDATE: MAKING THE BEST CHOICES FOR YOUR INSTITUTION

by

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Abstract

The National Institute of Health (NIH) rolled out the new single IRB (sIRB) on January 25, 2018. The single IRB allows institutions that participate in multi-site studies to be the overseers of the institutional review board of human subject participants. Prior to this rollout, most sites with multiple studies had their own IRB office conduct an independent review of studies that involved human subject research. The NIH realized that most sites submitted an application to the review board for the same study, which prompted their introduction of the single IRB. In this Capstone Project, the author developed a training guide to address researchers' questions regarding multi-site studies and the submission of human subject protocols. The revised human subject regulations determined that only specific studies that include non-exempt human subject research using funds from the NIH will be reviewed and considered for a single IRB protocol. The author of this Capstone Project developed several flow charts and scope of project guidelines that will provide researchers with the necessary information to successfully submit their multi-site applications to the NIH Institutional Review Board in a manner that will suit their project's and institution's best interests.

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Abbreviations

IRB: Institutional Review Board for the Protection of Human Subjects

NIH: National Institutes of Health

sIRB: Single Institutional Review Board

PI: Principal Investigator

SOM: Johns Hopkins University School of Medicine

JHURA: Johns Hopkins University of Research Administration Office

RATPAK: Johns Hopkins University Research Administration Training Program

HIRB: Johns Hopkins University Homewood Institutional Review Board

JHSPH: Johns Hopkins Bloomberg School of Public Health

JHMIRBs: Johns Hopkins Medicine Institutional Review Boards

FWA: Federal Wide Assurance

Glossary

IRB: an administrative body established to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. [1]

Common Rule: Pre-2018 Common Rule: A living individual about whom an investigator (whether professional or student) conducting research: i. Data through intervention or interaction with the individual; or ii. Identifiable private information. [2]

New Common Rule: Revised Common Rule: A living individual about whom an investigator (whether professional or student) conducting research: i. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or ii. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [3]

sIRB: The use of a single IRB of record for multi-site studies that are conducting the same protocol will help streamline the IRB review process by eliminating the unnecessary repetition of those reviews across sites. [4]

sIRB Plan: the Single Institutional Review Board plan is a document provided by Principal Investigators to NIH that includes specific requirements.

Principal Investigator: The individual(s) designated by the applicant organization/recipient to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. [5]

Human Subjects: Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals. [6]

Key Personnel: The personnel considered to be of primary importance who contribute to the scientific development or execution of a project. [7]

Federal Wide Assurance: The Federalwide Assurance is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by HHS.[8]

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[1] "1.2 Definition of Terms", accessed April 30, 2021, https://grant.nih.gov/grants/policy/nihgps/html5/section_1/1.2_definition_of_terms.htm.

[2] Ibid.

[3] "1.2 Definition of Terms", accessed April 30, 2021, https://grant.nih.gov/grants/policy/nihgps/html5/section_1/1.2_definition_of_terms.htm.

[4] "Single IRB Policy for Multi-Site Research | grants.nih.Gov," accessed April 30, 2021, https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm.

[5] "1.2 Definition of Terms", accessed April 30, 2021, https://grant.nih.gov/grants/policy/nihgps/html5/section_1/1.2_definition_of_terms.htm.

[6] Ibid.

[7] "Glossary of Terms and Acronyms | JHURA," accessed April 30, 2021, https://research.jhu.edu/jhura/training-and-resources/glossary-of-terms-and-acronyms/.

[8] "1.2 Definition of Terms", accessed April 30, 2021, https://grant.nih.gov/grants/policy/nihgps/html5/section_1/1.2_definition_of_terms.htm.

Chapter 1. Introduction

1.1. Background

At research universities, it is standard for two principal investigators (PIs) from different departments to collaborate on a research project. When two PIs choose to work together on a project, they will share knowledge and ideas. For instance, a PI from Johns Hopkins University School of Medicine decides to work with a PI from JHU School of Public Health on a cancer research project. The primary PI will be the one who received the funding from a government agency or foundation, and the second PI will be considered as the co-investigator on the project. The primary PI will apply to their JHU IRB office to obtain an IRB protocol to conduct research involving human subject participants.

All research universities receiving federal funds to support the research must comply with the Federal Policy for the Protection of Human Subjects Common Rule.

> The current U.S. system of protection for human research subjects is heavily influenced by the Belmont Report, written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report outlines the basic ethical principles in research involving human subjects. In 1981, with this report as foundational background, HHS and the Food and Drug Administration revised, and made as compatible as possible under their respective statutory authorities, their existing human subjects regulations. [9]

In 1991, the Federal Policy for the Protection of Human Subjects was published and "codified in separate regulations by 15 Federal departments and agencies." [10]

[9] "Federal Policy for the Protection of Human Subjects ('Common Rule ...", accessed April 30, 2021, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html.

[10] Ibid.

If a research university is conducting research similar to another research at a different institution, both PIs would submit an IRB application to their IRB office for review and approval. A new federal policy, called the Revised Common Rule, Single Institutional Review Board (sIRB), went into effect on January 25, 2018. The new common rule was designed to eliminate the review of the same protocol and designated one institution to oversee a single IRB protocol. All protocols from multiple sites and universities will fall under the single IRB record for the institution designated as the overseer.

Under the sIRB policy, issued by the US National Institutes of Health's (NIH) Office of Research Integrity, researchers engaged in collaborative research for multiple institutions must choose one university's IRB to review, approve, approve with modifications, or disapprove the collaborative protocol for human subjects. Designating one university to manage the human subjects is in accordance with NIH, new sIRB. The policy's primary purpose is to eliminate multiple protocols submitted to the institution IRB office for review.

The New NIH sIRB regulations have caused confusion about how research faculty and staff submit their IRB protocols when human subjects are involved in their projects. This capstone project is aimed to provide research faculty and staff with a guidance document on how to use the new sIRB process and procedures. After the NIH mandated the new sIRB policy, it left faculty and staff at universities and colleges baffled about the new policy and how to address the following questions: 1) Does the sIRB policy apply to my project? 2) Which IRB would be the best choice for

my project? and 3) How do I draft a plan for the use of a particular sIRB for my project? The proposed guidance document is designed to help research faculty and staff worldwide answer these three questions concerning the new sIRB mandate.

1.2. Statement of the Problem

Before the rollout of the sIRB, researchers from different universities submitted the same protocol for review to their local university IRB office, which created a modification to an existing protocol. This prompted NIH to develop and roll out the new Single Institutional Review Board. The policy's implementation and guidelines are "expected to reduce unnecessary administrative burdens and systemic inefficiencies while maintaining appropriate human subject protections." [11]

This project's critical challenge was to help faculty and staff respond to the three questions presented above. An additional issue addressed was how to equip researchers with the guidance and clarity they need as they prepare NIH applications for research funding relating to the sIRB. Another issue addressed focused on helping faculty and staff decide whether they should apply for the sIRB or if the protocol is better suited for review by another IRB. An additional issue addressed is equipping researchers with guidance and clarity as they prepare their sIRB protocol application. The guidance document, *"A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution,"* prepared under this Capstone Project provides researchers and research administrators with a scope of project guidelines and three

[11] "Single IRB Policy for Multi-Site Research | grants.nih.Gov," accessed April 30, 2021, https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm.

flowcharts for faculty and staff to address the problems they are faced with when submitting an sIRB Protocol. The critical problem that will be addressed throughout this Capstone Project is to help faculty and staff members at universities better understand the three questions in 1.1. Background.

An additional issue that will be addressed throughout this Capstone Project is supplying research faculty and staff with guidance and clarity when applying to NIH, "which under the Revised Common Rule requires that all grant applications for domestic, multi-site, non-exempt human subject research studies include a proposal for the use of a single IRB to review the research for all participating domestic sites".[12] Another issue that will be addressed in the Capstone Project is helping research faculty and staff decide whether they need to apply for the sIRB. The author will provide researchers and research administrators with a guidance document, *"A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution,"* that will include a checklist, concept mapping for faculty and staff members involved with human subject protocols. The guidance document will also help faculty and staff address problems they are faced with when submitting an sIRB protocol.

Johns Hopkins University has three IRB offices: Johns Hopkins University Homewood Institutional Review Board (HIRB), Johns Hopkins Medicine Institutional Review

[12] "NIH Single IRB Review FAQs | Johns Hopkins University," accessed April 30, 2021, https://homewoodirb.jhu.edu/about/nih-single-irb-review/.

Board (JHMIRB), and Johns Hopkins Bloomberg School of Public Health (JHSPHIRB), which are working together to address the new NIH requirement for sIRB. The Homewood IRB serves the Krieger School of Arts and Sciences, Whiting School of Engineering, School of Education, Carey Business School, Nitze School of Advanced International Studies, and Peabody Institute. "HIRB is responsible for reviewing all research projects involving human participants conducted in these divisions. This policy applies to all faculty, staff, and student research projects, whether or not a project is funded and regardless of the location at which the research will be conducted."[13]

The Johns Hopkins Medicine Institutional Review Boards

> are responsible for protecting the rights and welfare of the human subjects of research conducted by faculty and staff at the Institutions. The JHM IRBs review all human subjects research projects conducted by Hopkins faculty and staff. To fulfill the agreement underlying the assurances, and to satisfy institutional policy, all faculty and staff at the Institutions must submit for JHM IRB review any human subject research project, regardless of funding source (or lack thereof) and/or location at which the research will be conducted.[14]

Johns Hopkins Bloomberg School of Public Health has two active IRB offices (IRB X and IRB FC). Johns Hopkins Bloomberg School of Public Health (JHSPH) serves Biochemistry and Molecular Biology, Biostatistics, Environmental Health and Engineering, Epidemiology, Health, Behavior and Society, Health Policy and Management, International Health, Mental Health, W. Harry Feinstone Department of Molecular Microbiology and Immunology, and

[13] "Homewood Institutional Review Board | Johns Hopkins University," accessed April 30, 2021, https://homewoodirb.jhu.edu/.

[14] "Johns Hopkins Medicine Institutional Review Board (IRB)," accessed April 30, 2021, https://www.hopkinsmedicine.org/institutional_review_board/.

Population, Family and Reproductive Health. The JHSPH IRB is responsible for "all faculty and students to ensure that they obtain IRB approval or exempt determination before initiating any human subjects research project." [15]

Johns Hopkins School of Medicine is currently approved for a total of 60 sIRBs protocols and participating with more than two multi-sites. JHM has a total of 60 sIRB's because they are designated to oversee the sIRB process. When a sponsor requires sIRB services, and a JHU PI wants JHU to serve as the study's sIRB, the Johns Hopkins School of Medicine IRB office will review all requests for sIRB services, and if approved, will serve as the University's sIRB for all divisions. JHU has signed on to the smart IRB Reliance agreement, and investigators are urged to make sure that their collaborators have either signed on to this form of reliance agreement or are willing to sign on.

Research faculty and staff must include the sIRB plan within the human subject part of the grant application for NIH funding. All Planning Phase and New Applications that involve Hopkins as the reviewing sIRB must submit a "Reliance Request" through an online Johns Hopkins School of Medicine IRB query portal. A reliance agreement is a "written document that provides a mechanism for an institution engages in research to delegate institutional review board (IRB) review to an independent IRB or an IRB of another institution."[16] Before one institution can be designated as the sIRB, "reliance agreements must be executed between the sIRB and each other site relying on the sIRB."[17]

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[15] "JH Bloomberg School of Public Health. "Institutional Review Board." Johns Hopkins Bloomberg School of Public Health. Last modified April, 7, 2021. https:///www.jhsph.edu/offices-and-services/institutional-review-board/.

[16] "Johns Hopkins Medicine Reliance Agreements," accessed April 30, 2021, https://www.hopkinsmedicine.org/institutional_review_board/about/agreements/.

[17] "Single IRB & Exceptions Process Webinar | grants.nih.Gov," accessed April 30, 2021, https://grants.nih.gov/grants/webinar_docs/webinar_20171018.htm.

The Reliance agreement, also called an authorization agreement, should be completed by either the PI or someone the PI has authorized to submit on his/her behalf. The PI or the person authorized by the PI will complete a reliance request to their institution IRB Office. The institution IRB Office will review the submission and contact the PI or the authorized person with the next steps and instructions. All institutions must agree to the terms of the reliance agreement before they can start completing their research project involved in human subjects research.

Only institutions with a federal-wide assurance number can serve as an sIRB. Federal-wide assurance "is an assurance of compliance with the U.S. Federal regulations for the protection of human subjects in research."[18] The sIRB plan must explain the use of the sIRB and identify the institution that's serving as the sIRB. In regulations**, "**Applicants/offerors will be expected to submit a plan identifying the sIRB that will serve as the IRB of record for all study sites." [19] The sIRB plan is required and needed because it is an attachment with no page limit explaining in detail the university that will oversee the project and including all sites associated with the project under the sIRB.

[18] Federalwide Assurance Instructions | HHS.Gov", accessed April 30, 2021, https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas-forms/fwa- instructions/index.html

[19] "NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional ...", accessed April 30, 2021, https://grants.nih.gov/grants/guide/notice-files/not-od-16-094.html.

On October 18, 2017, "NIH hosted a webinar that was designed for anyone interested in learning more about the implementation of the NIH Single IRB Policy, including principal investigators, signing officials, research organizations or institutions, and institutional review boards (IRBs)." [20] The purpose of the webinar was for participants to learn how to implement the NIH single IRB policy, understand the expectations for the NIH single IRB policy, become familiar with the process to request exceptions to the policy, and understand the responsibilities of the IRB, the investigator, and the institutions in implementing the NIH single IRB policy. [21] On October 18, 2017, NIH held a webinar on "Single IRB & Exceptions Process to Provide information to everyone interested in learning more about the implantation of the new NIH sIRB Policy.

The participants learned about the following:

> 1) learn how to implement the NIH Single IRB Policy, 2) Understand the expectations for the NIH Single IRB Policy, 3) Become familiar with the process to request expectations to the policy, and 4) Understand the responsibilities of the IRB, the investigator, and the institutions in implementing the NIH single IRB policy. [22]

The NIH website has FAQs titled the "Implementation of the sIRB Policy," a total of fifty-nine questions is broken into sections. The nine sections are as follows:

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[20] "Single IRB and IRB Reliance Agreements," accessed April 30, 2021, https://extranet.fredhutch.org/en/u/irb/sirb/html.

[21] Ibid.

[22] "Single IRB & Exceptions Process Webinar | grants.nih.Gov," accessed April 30, 2021, https://grants.nih.gov/grants/webinar_docs/webinar_20171018.htm.

1)Policy Background and General Requirement, 2) Policy Terms and Definitions, 3) Policy Applicability, 4) NIH Grant Application/Contract Proposal Preparation, 5) Reliance Agreements, 6) Responsibilities of the Single IRB and Participating Sites, 7) Award Consideration (Just-in-Time), 8) After the Initial Award, and 9) Exception to the NIH Single IRB Policy. [23]

1.3. Project Question

In the Capstone Project, the author aimed to create a guide, *"A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution,"* that will guide researchers throughout the sIRB protocol process, so that they don't run across any issues such as delays, the protocol being returned for edits, or the protocol being disapproved. The guide, *"A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution,"* developed a scope of project guidelines and flowcharts to help research faculty and staff submit their applications without struggling to answer the project questions in subsection 1.1. Background.

1.4. Project Objective

The main goal of the Capstone Project objective was to develop materials that will be beneficial to research faculty and staff worldwide and Johns Hopkins University. *A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution* will help research faculty and staff determine the best IRB that will be suitable for their project. The information gathered in "*A Guide to Compliance with the Single*

[23] Implementation of the SIRB Policy-Office of Science Policy", accessed April 30, 2021, https://osp.od.nih.gov/clinical-research/implementation-of-the-sirb-policy/.

IRB Mandate: Making the Best Choices for Your Institution" also helps research faculty and staff apply for and submit the IRB suitable for their project to their respective local IRB Office. The project further sought to provide research faculty and staff with decision-making support, processes, knowledge, and data on how to submit an sIRB application for approval. To prepare research faculty and staff to submit an sIRB application, *"A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution,"* is equipped with adequate information to help them throughout the process.

1.5. Significance

This Capstone Project's importance is providing research faculty and staff with information to guide them when applying to the sIRB. The project also includes a training guide, "*A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution,"* to minimize tension on the part of research faculty and staff worldwide and at JHU when addressing specific questions about the sIRB. The guidance document also includes information about ethics, standards, and morals beneficial to the faculty and staff conducting research using human subjects. This project is essential to the author's institution because it will be the blueprint for research offices at Johns Hopkins University (JHU), including Johns Hopkins University Research Administration Office. This project is also vital to the author's organization because, while JHU has several research administration offices, the School of Medicine was designated as the office to oversee the sIRB.

1.6. Exclusions and Limitations

The guidance document, *"A Guide to Compliance with the Single IRB Mandate Making the Best Choice for Your Institution,"* will be helpful to researchers worldwide.

The scope of the project guidelines and flowcharts included in the guidance document is designed to guide research faculty and staff on submitting a protocol and drafting a plan. Research faculty and staff members have found it challenging to complete an application to obtain an sIRB Protocol. Due to the exclusion and limitations in determining which university will house and manage the sIRB protocol, the guidance document will not determine which university will be chosen to manage the sIRB protocol.

Chapter 2. Literature Review

The purposes of this literature review are as follows:

1. To address the sIRB Policy,
2. To address critical factors in determining which IRB will be the best choice for a given project, and
3. To address the mechanics of drafting an sIRB plan for inclusion in a proposal submitted by JHU to NIH for funding consideration.

2.1. Overview of Literature Review

All applications partaking in a multi-site study human subject protocol submitted after January 25, 2018, will automatically be reviewed according to this new sIRB policy. All domestic sites participating in a multi-site study under the same protocol must follow the sIRB policy. This policy doesn't apply to fellowship awards, research training, and/or career development. By implementing this new sIRB policy, the NIH's core intent is to condense administrative burdens on instructional review board members and their peers.[24]

The NIH sIRB Policy provides several vital factors to help researchers determine which IRB will be best suited for their project. These are the key elements of the policy: Does the project involve research? Will human subjects be utilized throughout the project? Does the project fall under the multiply study site category? Drafting an sIRB can be overwhelming and complicated because of all the information required by the NIH that must be included in the plan. The information that should be included in the sIRB plan includes the following:

- A description of compliance to the NIH sIRB policy.

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[24] "Single Institutional Review Board (sIRB) | Guidance Portal," accessed April 30, 2021, https://www.hhs.gov/guidance/document/single-institutional-review-board- sirb.

[25] "Single IRB Policy for Multi-Site Research | grants.nih.Gov," accessed April 30, 2021, https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm.

- The name of the IRB that will serve as the sIRB of record.
- An indication that all identified participating sites have agreed to rely on the proposed sIRB and that any sites added after award will rely on the sIRB.
- A brief description of how communication between sites and the sIRB will be handled.
- An indication that all participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
- Stipulation of which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan. [16]

2.2. Literature Review

The literature review for this project addresses the concept of the new sIRB and provides overall guidance to help researchers determine which IRB would be the best suited for their project. NIH's primary justification for mandating the sIRB is that it is more practical to have multiple IRB policies under the same protocol.

> The evidence to support the effectiveness of sIRB review is limited by the lack of standardized outcome measures. In addition to supporting the implementation of the sIRB policy at U.S. institutions, stakeholders should also invest in evaluating the utility of sIRB review. Evaluation of sIRB outcome data would support or refute the value of this systematic approach to streamlining multicenter ethical review and would also inform any modifications to the policy going forward. Reliable measures to assess quality are key first steps, and the development and pilot testing of related outcomes are essential prior to widespread implementation of the sIRB policy. [26]

A webinar was held by The National Council of University Research Administrators (NCURA) to provide research faculty and staff worldwide with an overview of the requirements of the new sIRB policy for multi-site research studies. The New World

[26] "A Measure of Effectiveness is Key to the Success of SIRB Policy," accessed April 30, 2021. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5568650/.

of Single IRBs: Single IRB Under the NIH Policy and Revised Common Rule webinar provides an overview of the requirements of the NIH Policy on the Use of a Single IRB (sIRB) for Multi-Site Research. The webinar also discussed the revised Federal Policy for the Protection of Human Subjects (Common Rule) and addressed questions institutions had regarding the new sIRB mandate. The Society Research Administrators International posted an article about five core strategies for implementing the new NIH sIRB Policy.[27] Implementing the NIH Single IRB Policy: Five Core Strategies are as follows: Conduct a Portfolio Review, Determine who will serve as the sIRB, Determine Associated Cost (s), Identify Business Processes that Need Creating/Updating, and Evaluate Technology Options. They are important because of the diverse responses to the new mandated Single Institutional Review Board Policy.[28]

2.3. Applicability of Literature Review

The literature review applies to the project because it provides researchers with greater knowledge and resources. This literature review's findings help researchers whose projects use human subjects participants to navigate the IRB, Common Rule, and the sIRB process. The literature review further applies to this project by guiding researchers of all experience levels through the new NIH sIRB Policy. NIH regulation is

[27] "The New World of Single IRBs: Single IRB…-NCURA Online Learning", Accessed April 30, 2021, https://onlinelearning.ncura.edu/products/the-new-world-of-single-irb- under-the-nih-policy-and-revised-common-rule.

[28] "NIH SIRB Strategies | Clic," accessed April 30, 2021, https://clic- ctsa.org/taxonomy/term/1246

"to enhance and streamline the IRB review process for multi-site research so that research can proceed as quickly as possible without compromising ethical principles and protections for human research participants." [29] The article, The Final Rule: When the Rubber Meets the Road, summarized the new common rule, and provided changes that would require attention from researchers worldwide such as changes to "the informed consent form and the use of single IRBs for domestic multi-site research, and changes to continuing review requirements." [30]

The article discusses increasing the scope and coverage of the IRB process. With increasing the range of the IRB process, the Federal Wide Assurance (FWA) must be increased to offset non-federal research. "The preamble to the revised final rule describes a plan to implement the proposed nonregulatory change to the assurance mechanism to eliminate the voluntary extension of the FWA to non-federally funded research (FR 7156)". Institutions would have to develop policies that describe the scope of research that they plan to cover and which elements of the final rule would be applied to nonfederal research." [31] Another literature review is offering coverage to non-federal wide assurance institutions by "extending coverage to commercial, institutional

[29] "Single IRB Policy for Multi-Site Research | grants.nih.Gov," accessed April 30, 2021, https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm.

[30] O'Rourke, P.P. "The Final Rule: When the Rubber Meets the Road." The American Journal of Bioethics 17, no. 7 (2017), 27-33. Doi:10.1080/15265161.2017.1329484

[31] Ibid.

[32] O'Rourke, P.P. "The Final Rule: When the Rubber Meets the Road." The American Journal of Bioethics 17, no. 7 (2017), 27-33. Doi:10.1080/15265161.2017.1329484

nonfederal research." [32] Another literature review is offering coverage to non-federal wide assurance institutions by "extending coverage to commercial, institutional review boards (IRBs), also known as independent IRBs (iIRBs) (_.101(a)). In the pre-2018 rule, IRBs not situated at an FWA-holding institution, such as iIRBs, were not held responsible for compliance with the Common Rule, a rather disquieting concept for institutions that relied on iIRBs. This is a significant improvement." [33]

[33] O'Rourke, P.P. "The Final Rule: When the Rubber Meets the Road." The American Journal of Bioethics 17, no. 7 (2017), 27-33. Doi:10.1080/15265161.2017.1329484

Chapter 3. Need (s) Assessment

3.1. Need (s) Assessment

Every research administration office inevitably struggles to help research faculty and staff choose the best IRB to suit their needs, and the PI or their designee draft a plan for the sIRB. The sIRB Plan is prepared by the principal investigator and submitted with their grant application. The challenge for research faculty and staff was determining which one would produce a viable project for principal investigators worldwide. Gathering information and analyzing research faculty and staff needs was the primary objective during this project's design. The author shared their ideas with co-workers to develop a project that would be helpful to the research world as a whole.

3.1.1. Establishing the Need

Extensive research and consideration of several alternatives played an essential role in assessing project needs. This process involved defining the scope, determining the guidance's usefulness, and evaluating the potential outcome to determine the kind of guidance required. Close consultation with co-workers also played a significant role in determining the Capstone Project requirements. The Capstone Project's scope determined the needs of "*A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution*" and how it will help the overall research world. In this case, the Capstone Project was designed to provide "*A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution*" that will

be useful to research faculty and staff worldwide and at JHU.

3.2. Metrics

The scope of the Capstone Project helped to establish the need for this project. The project requirements potential benefits to research faculty and staff, the project's potential value to the research world, and the extent of collaboration with researchers in other institutions are examples of project success metrics. Together, these comprise the overall metric of customer satisfaction.

3.3. Sources

Several individuals (advisor, mentor, and co-workers) helped develop this project's need and scope. Everyone provided critical feedback and ideas on how the project would benefit the research world as a whole. They also provided significant insight and resources that were vital throughout this project.

3.4. Committees

The committee assisting in assessing this project's need included co-workers and the person chosen as a mentor. This group provided essential guidance throughout this project. After initial formulation of the project scope, review and comments were solicited via emails or chats using Microsoft Team software. Each person submitted their comments and opinions, which were vital to the final project scope.

3.4.1. The Role the Committee

Ultimately, the committee played a significant role in refining the project scope and defining how the guidance document could assist the research

administration in responding to the requirements of the sIRB.

Chapter 4. Project Description

4.1. Project Elements

The project was designed to develop a guidance document that will help research faculty and staff select the best IRB choice for their research project. The author created a six-page guidance document that contains vital elements regarding the IRB and sIRB process and the sIRB Plan development. The guidance document's importance is tailored towards the new common rule mandate that went into effect in January 2018. The guidance documents' design consists of three flow charts (IRB, sIRB, and sIRB plan) and scope of project guidelines.

The elements of each flow chart came from different information listed on the NIH website. The key information pulled from the NIH website, the author turned the data into statements that will help guide research faculty and staff worldwide and at JHU prepare for the submission of an sIRB protocol and the drafting of an sIRB plan. The author formulated the data to develop statements to create each flow chart and the scope of project guidelines. The project was designed to be beneficial to research faculty and staff worldwide and at JHU. By implementing and following each flow chart (IRB, sIRB, and sIRB Plan) when choosing the IRB choice best for their research project, faculty and staff should be able to breeze through the application process. In *"A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution,"* the guideline's scope was designed to help research faculty and staff choose the IRB that's suitable for their project.

Chapter 5. Methodology

5.1. Methodology Overview

This chapter describes the methodologies used to conduct and complete the guidance document, including flow charts illustrating the requirements for submitting an IRB and sIRB application, requirements for drafting a sIRB Plan, and scope of project guideline checklist.

5.1.1. Design of the Methodologies

The guidance document was designed to provide research faculty and staff members with a written document to refer to when submitting an sIRB application. The purpose of designing the flow charts was to provide faculty and staff who want to work with human subjects in research with the necessary information to submit their IRB or sIRB application to the NIH Institutional Review Board. The flowcharts and scope of the project guideline checklist consist of statements that helps guide them through the IRB and sIRB process and draft an sIRB plan. Each flowchart was designed to help research faculty and staff gather the necessary to complete the protocol application process and make sure they don't submit an incomplete protocol application or sIRB plan.

The methodology of designing the scope of the project guideline checklist was to provide research faculty and staff with a concrete document they can use when submitting an sIRB application for approval to their IRB office for review. It

was designed to be a framework that can assist them in ensuring that they have answered all the application questions correctly and provide all the necessary documents before submitting the protocol to their IRB office for approval.

The methodology of including the sIRB Plan requirements is one way of aiding research faculty and staff to acquire information that must be included in their sIRB Plan. Because an sIRB Plan is required, drafting a plan is compulsory before submitting their grant application to the NIH Institutional Review Board. Including crucial data on how to outline an sIRB Plan will be valuable to research faculty and staff worldwide.

5.2. Project Design and Discussion

Several important steps have been identified for the flow charts to help guide research faculty and staff members through the IRB and sIRB application process. The flowcharts are the Institutional Review Board (IRB), Single Institutional Review Board (sIRB), and sIRB Plan Required Information. Each flow chart consists of several different important steps to help guide research faculty and staff when considering and applying for a specific IRB and drafting an sIRB plan when human subjects are involved in their project. All of the steps in each flowchart guide research faculty and staff with the necessary information they need to complete an IRB or sIRB from the beginning to the end. The flow chart elements are statements put together to help research faculty and staff submit an accurate IRB application. For the checklist, the guideline scope consists of four sections that have been created to help navigate research faculty and staff throughout the planning phase process.

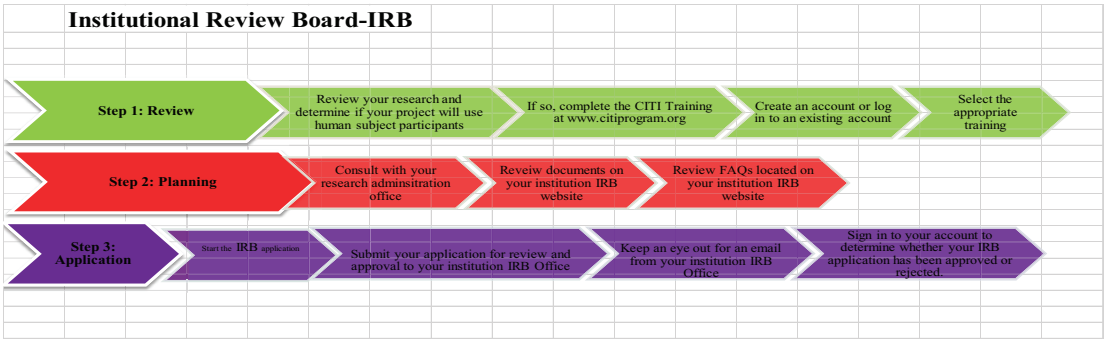
In the IRB flow chart, the author developed a three-step flowchart to help guide

research faculty and staff worldwide and at JHU when applying for approval to their institution's IRB office. Review, planning, and application make up the elements in the IRB flowchart. The review step has four phases that help researchers determine if their project will utilize human subjects and how to complete the proper training. The planning step consists of three phases that help researchers complete the next steps after determining if human subjects will be utilized on their project. The application step has four phrases to help guide research faculty and staff worldwide and at JHU through the submission process of an IRB application to their IRB Office. In the sIRB flow chart, the author created a four-step flowchart to help guide research faculty and staff worldwide and at JHU to submit a protocol for consideration.

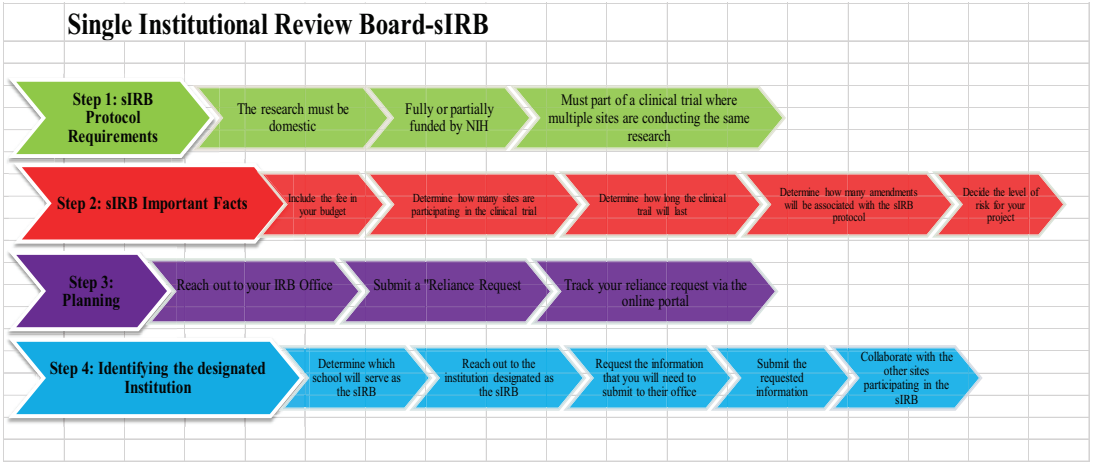
The sIRB protocol requirements consist of three essential phases on how research faculty and staff can determine if their research project will be associated with an sIRB protocol. The sIRB important facts comprise five critical phases each research faculty and staff worldwide must know about the sIRB protocol. The planning step consists of three phases each research faculty and staff must do after submitting the protocol for approval. Identifying the designated institution consists of four phases to help researchers determine who institution was designated as the overseer of the protocol. The sIRB Plan Required Information flow chart was designed to support research faculty and staff worldwide and at JHU draft an effective plan.

The sIRB Plan Required Information flow chart consists of the required information, requirements for drafting the sIRB Plan, and submitting the sIRB Plan Required Information flow chart. The Required Information is three essential steps each researcher must do once their sIRB protocol has been approved. The requirements for drafting the sIRB plan are critical phases of important information research faculty and

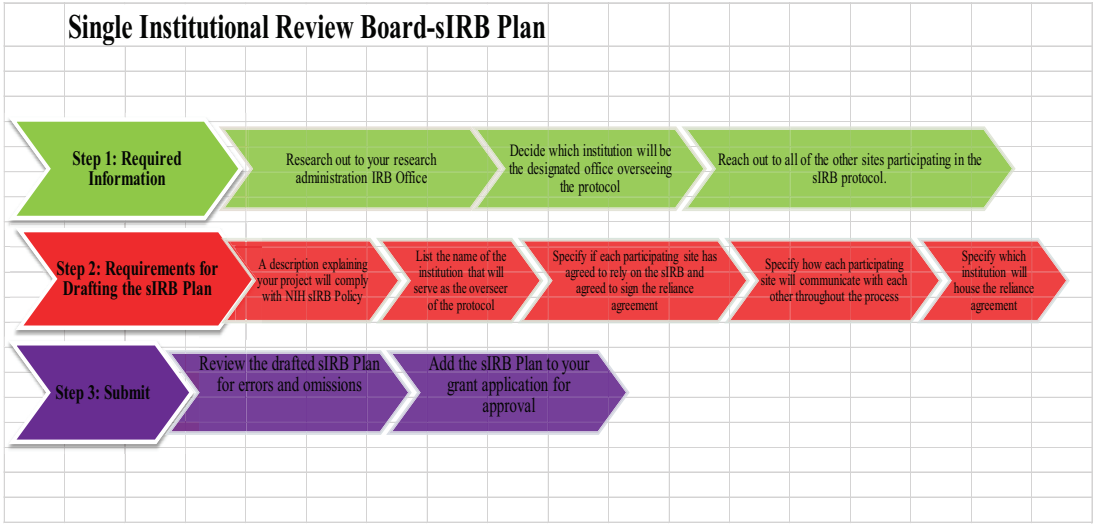
staff must include in their sIRB plan. The submitting steps consist of two steps before submitting the protocol and grant application for approval.



Flowchart 1: The Institutional Review Board-IRB



Flowchart 2: The Single Institutional Review Board-sIRB



Flowchart 3: The Single Institutional Review Board-sIRB Plan Required Information

The checklist gives researchers a self-assessment tool they can use to determine if their project will utilize human subjects. “The Project,” “Plan/Prepare,” “Review,” and “Submit” are the four components that comprise the checklist. Each component consists of bulleted information points that help readers confirm that every part of the application is complete before submitting.

Below are the elements used to establish the checklist.

Project

- Identify the project requirements.
- Define the scope.
- Determine the critical points.
- Gather information and resources.
- Analyze the need for the project.
- Based on a review of the IRB flowchart, determine if the project will use human subjects.
- Research the IRB Protocols to decide which is most suitable for the project.

Prepare the Application

- Once the correct IRB protocol for the project has been selected, begin gathering the necessary information required to complete the application.
- If help is needed in choosing the correct IRB protocol, contact the Research Administration Office at your institution, the NIH IRB Office, or refer back to “*A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution.”*

Review

- Review the application for completeness.
- If a particular section is incomplete, complete it promptly.
- If help is needed with completing a section of the application, reach out to the administration contact person in your Research Administration Office.

Submit

- Submit your application to your IRB Office for approval.

Chapter 6. Projects Results and Discussion

This project's results made it possible to develop a guide to help research faculty and staff make the best choices for their institution when determining which Institutional Review Board is the most suitable for their projects. Such guidance is established to provide the necessary information to help researchers throughout the application process. The guide also offers essential material concerning the new single institutional review board mandate. The guidance consists of a checklist, flowcharts, and imperative components of drafting an sIRB plan and requirements for the sIRB.

6.1. Project Results

Scope of project guideline checklist has been created to help research faculty and staff during the IRB and sIRB processes. The checklist comprises four sections of essential elements needed to help guide them from the beginning to the end.

6.2. Project Results

The guide includes three flowcharts related to critical elements that research faculty and staff can consult when submitting their IRB and sIRB application for approval or drafting a SIRB plan. These elements should also assist research faculty and staff worldwide by giving them a guide to follow when gathering and preparing the necessary information for approval for their application. Ideally, the flowchart elements will help them secure approval from the NIH Institutional Review Board without the need for additional edits or being overwhelmed by the process.

Chapter 7. Recommendations and Discussion

7.1. Introduction

This capstone project led to the development of "*A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution,"* in hopes of identifying the researcher's deficiencies and overcoming a lack of certainty when submitting an IRB or sIRB application or drafting an sIRB plan. It is recommended that research faculty and staff implement the checklist and flowcharts into their process when human subjects will be used in their projects.

7.2. Recommendations

7.2.1 Recommendation 1: Researchers and staff submitting sIRB human subject protocols and creating sIRB plans for inclusion in their proposal submission to NIH should use the Scope of Guidelines Checklist provided in the "*A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution."*

The checklist equips each research faculty and staff member by assisting them in selecting which IRB is most suitable for their project and institution. This information could be of use to research faculty and staff around the world. The flowcharts and checklist provide valuable information to help them maneuver through the process of completing an IRB application. The checklist emphasizes the significance of determining if human subjects will be used in their project.

7.2.2. Recommendation 2: Researchers and staff submitting sIRB human

subject protocols and creating sIRB plans for inclusion in their proposal submission to NIH should use Flowchart 2: the Single Institutional Review Board-SIRB Flowchart and Flowchart 3: the Single Institutional Review Board Plan Flowchart provided in the *"A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution."*

Researchers and staff can ensure that the process of submitting an sIRB application and sIRB Plan goes smoothly are by incorporating each of the flowcharts from *"A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution."* The sIRB flowchart is recommended because it will guide research faculty and staff worldwide and at JHU through the sIRB protocol submission. The sIRB Plan flowchart is recommended because it provides research faculty and staff with the important information to draft an sIRB plan.

Chapter 8: Conclusion

By working in a research administration office at one of the top research universities, Johns Hopkins University, the author was able to reach out to two co-workers (a supervisor and the Director of Export Control) and a mentor to determine if there were a specific project they could think of that would be beneficial to the world of research. One of the main concerns they mentioned was that most research faculty and staff struggle when drafting sIRB plans. This led to the creation of a guide that would be valuable to research faculty around the world.

The result of this capstone project is *A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution*. The guide covers elements in three flowcharts and includes a scope of project guidelines checklist to help researchers navigate the IRB and SIRB processes. It also helps users to decide if their research should include human subjects.

The data in *A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution* were gathered by asking co-workers at Johns Hopkins University questions regarding the sIRB mandate. The guide's primary focus is on providing faculty and staff with a blueprint they can refer to when submitting an application for approval or drafting an sIRB plan if their project is associated with a multi-site study.

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Appendix 1.

A Guide to Compliance with the Single IRB Mandate: Making the Best Choices for Your Institution.

By

Hershea Watson

Table of Content

Introduction

A Guide to Compliance with the Single IRB Mandate-Making the Best Choices for your Institution was designed to provide research faculty and staff with guidance to refer to when submitting an IRB application, sIRB application, and draft an sIRB plan. This guide should be able to help research faculty and staff worldwide with answering the following questions: 1) Does the sIRB policy apply to my project, 2) Which IRB would be the best choice for my project, and 3) How do I draft a plan for the use of a particular sIRB for my project?

Scope of Project Guideline

The Scope of Project Guideline consists of four sections to help research faculty and staff worldwide navigate the planning phase of conducting research. The scope of the Project guideline gives researchers a self-assessment tool they can use to determine if their research project will utilize human subjects.

Project

- Identify the project requirements.
- Define the scope.
- Determine the critical points.
- Gather information and resources.
- Analyze the need for the project.
- Based on a review of the IRB flowchart, determine if the project will use human subjects.
- Research the IRB protocols to decide which is most suitable for the project.

Prepare the Application

- Once the correct IRB protocol for the project has been selected, begin gathering the necessary information required to complete the application.
- If help is needed in choosing the correct IRB protocol, contact the Research Administration Office at your institution, or refer back to "*A Guide to Compliance with the Single IRB Mandate Making the Best Choices for Your Institution*."

Review

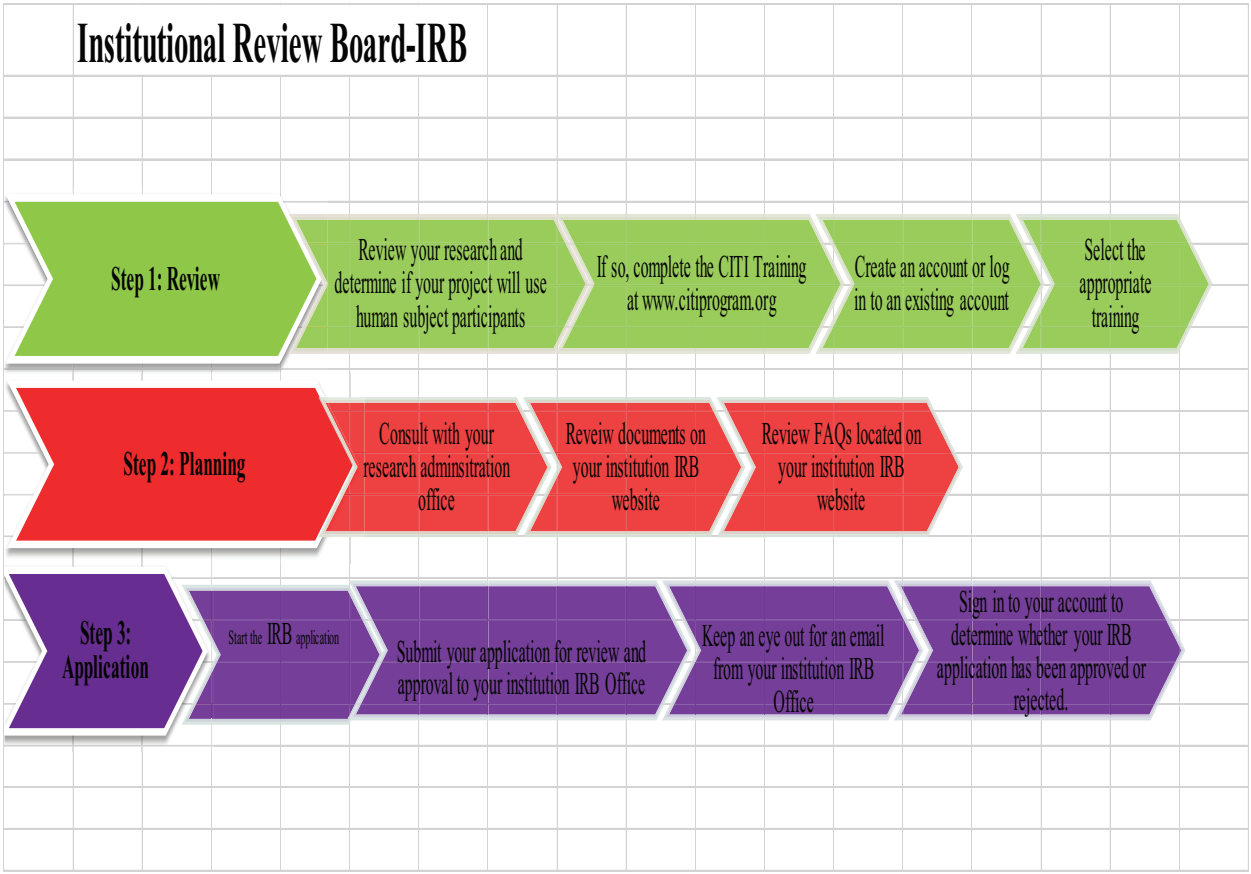
- Review the application for completeness.
- If a particular section is incomplete, please complete it in a timely manner.
- If help is needed with completing a section of the application, please reach out to the administration contact person in your Research Administration Office.

Submit

- Submit the application to the NIH Institutional Review Board for review.

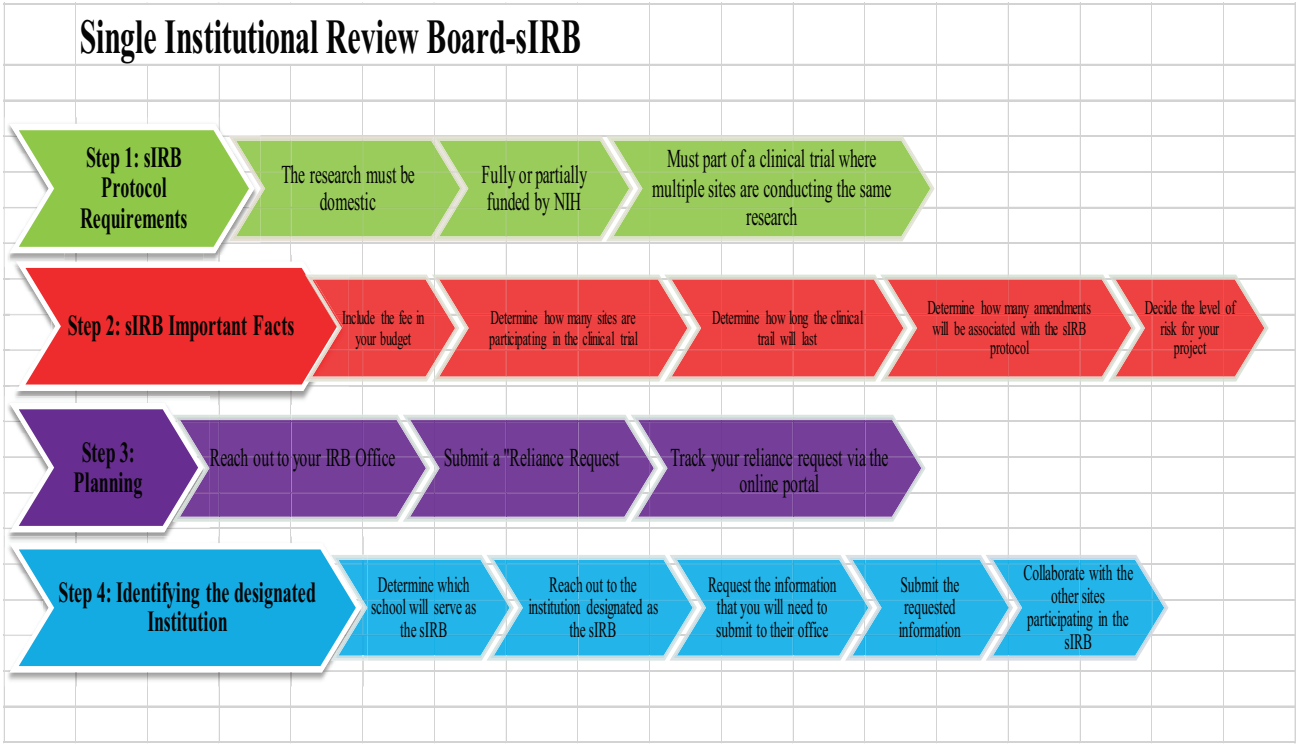
Institutional Review Board-IRB Flowchart

The Institutional Review Board was established to protect the rights of human subject participants. When human subject participants are utilized in a research project, the PI conducting the research must submit an IRB protocol application to their IRB office. The author developed a three-step flowchart to help guide research faculty and staff worldwide and at JHU when applying for approval to their institution IRB office. Each step in the IRB flowchart provides research faculty and staff with vital information to help guide them throughout the process.



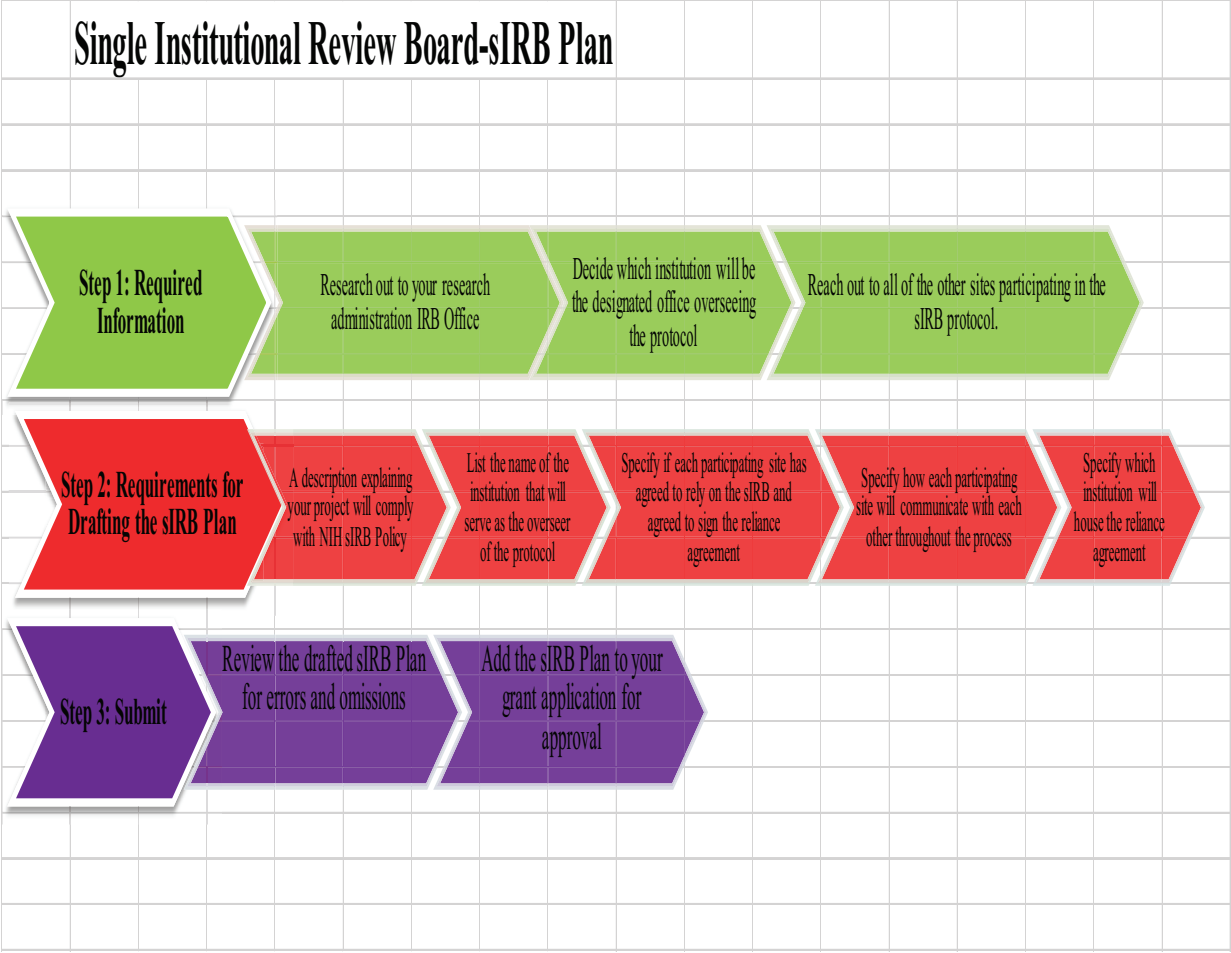
Single Institutional Review Board-sIRB Flowchart

On January 25, 2018, the NIH implemented the new Single Institutional Review Board policy. The author created a four-step flowchart to help guide research faculty and staff worldwide and at JHU submit a protocol for consideration. Protocol requirements, sIRB important facts, planning, and identifying the designated institution are the four steps put together to help research faculty and staff submit an accurate sIRB application.



Single Institutional Review Board Plan Flowchart

One of the most significant issues PIs was faced with was drafting an sIRB plan. The sIRB Plan Flowchart was designed to help research faculty and staff worldwide and at JHU draft an effective plan. The sIRB plan flowchart consists of three steps. Required information, requirements for drafting the sIRB plan, and submit are the three steps put together to help research faculty and staff worldwide submit an accurate sIRB plan with their grant application to NIH.



Appendix 2. Short Biography

Hershea Watson is the Sponsored Project Specialist-Subawards at the Johns Hopkins University Research Administration Office (JHURA) in Baltimore, Maryland. At JHURA, she is the first point of contact for subwards triage for departmental workflow action and supports the team by drafting new and modification sub- agreements. Hershea is a part of the Research Administration Training Program (RATPAK) while purchasing an M.S. in Research Administration at Johns Hopkins. She holds a B.S. in biology from the Selma University in Selma, Alabama.